Full Text PA-96-001

INVESTIGATOR-INITIATED INTERACTIVE RESEARCH PROJECT GRANTS

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National Institute on Alcohol Abuse and Alcoholism
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National Institute of Arthritis and Musculoskeletal and Skin Diseases
National Cancer Institute
National Institute of Child Health and Human Development
National Institute of Dental Research
National Institute of Diabetes and Digestive and Kidney Diseases
National Institute of Environmental Health Sciences
National Library of Medicine
National Institute of Mental Health
National Institute of Nursing Research
National Center for Research Resources

Application Receipt Dates: February 15, June 15, and October 15

PURPOSE

The Interactive Research Project Grant (IRPG) program provides support for formal, investigator-initiated, collaborative relationships. The IRPG program was announced in the NIH Guide for Grants and Contracts (Vol. 21, No. 16, April 23, 1993) and later revised (Vol. 23, No. 28, July 29, 1994). This revision contains the Instructions for Preparing Applications for an IRPG Group that

are compatible with the revised PHS 398 (rev. 5/95) application form and supersedes the previous Program Announcements (PA).

An IRPG group consists of the coordinated submission of two or more applications for related research project grants (R01) and, to a limited extent, First Independent Research and Support Transition (FIRST) awards (R29) that do not require extensive shared physical resources. Although these applications must describe the objectives and scientific importance of the collaboration, each project could be accomplished independently. The principal investigators may be from one or more institutions. Each application will be reviewed independently for scientific merit and those judged to have substantial merit will be considered for funding both as an independent award and as a component of the proposed IRPG group.

This PA includes a description of NIH policies and procedures for the preparation and review of applications for IRPG groups, including instructions to applicants that supplement the instructions in form PHS 398 (rev. 5/95). In addition to meeting the requirements of form PHS 398, each R29 and R01 application in the IRPG group must contain identical information about the IRPG group in the Research Plan and Consultants/Collaborators Section.

ELIGIBILITY REQUIREMENTS

Applications may be submitted by foreign and domestic, for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, State and local governments, and eligible agencies of the Federal government. Foreign institutions, however, are only eligible for the R01 award mechanism and an award to a foreign institution may be for no more than three years. Applications for a group may be from one or more institutions.

Applications for IRPG groups may not represent significant duplication of concurrent applications for a research project grant (R01) FIRST Award (R29), program project (P01), center (P50), or cooperative agreement (U-series).

MECHANISM OF SUPPORT

An IRPG group must include a minimum of two independent applications, R01 and R29 or only R01, but not only R29, applications. Applications for both new (Type 1) and competing renewal (Type 2) awards may be submitted as part of an IRPG group.

An NIH institute or center may issue a PA or RFA that encourages the submission of applications for IRPG groups. Applications for IRPG groups that are submitted in response to an RFA must be prepared and submitted according to the requirements of that RFA. The applications will be reviewed for scientific and technical merit and award decisions will be made according to the criteria and procedures described in the RFA.

Public Health Service (PHS) and NIH grants policies apply to IRPG applications and awards.

RESEARCH OBJECTIVES

Any research area supported by the NIH institutes and centers issuing this PA may be addressed by the applications of an investigator-initiated IRPG group. Each application submitted as part of an IRPG group must be tightly focused, and the interactions and benefits of the proposed links between projects must be explicitly described. An IRPG group could be used constructively to support collaborative efforts to accelerate the development of fundamental knowledge and/or enhance the clinical application of that knowledge. The IRPG program may provide an effective means to fund applications for focused clinical research and related, correlative laboratory studies. However, the IRPG program is not appropriate for large epidemiologic studies or for multi-institutional clinical trials using common protocols.

Historically, the NIH has relied on multi-component awards, such as program projects (P01), center grants (P-series), and cooperative agreements (U-series), to encourage multidisciplinary collaboration in areas requiring integration and central direction of basic and clinical research components. Program projects and center grants have a well-defined central theme, include extensive shared resources or core facilities, and are led by a principal investigator who has the authority and responsibility to manage the overall research effort and budget.

However, for many research areas, an intermediate level of collaboration may be appropriate. For some scientifically based collaborative efforts, the exchange of data, materials, and ideas is more important than extensive, shared, physical resources or central oversight. The IRPG program is meant to foster this category of research activity.

An IRPG group consists of a set of investigator-initiated applications for independent research on related topics, with a formalized agreement to collaborate in specific ways to enhance the achievement of the goals of all of the projects. The collaboration may involve limited shared resources. The IRPG, therefore, offers a means of promoting collaborative efforts between or among projects that are scientifically related, while providing a record of independently obtained

awards and retaining the research autonomy of each principal investigator. Each principal investigator may apply for competing supplements to support promising new research directions as they evolve. Other benefits of the IRPG program include the establishment of collaborations on an equal footing at separate sites (including foreign locations) and the possibility of transferring an award with the principal investigator to another institution without disrupting the IRPG group. Furthermore, each participating investigator may benefit because the IRPG establishes a larger framework of reference for the proposed work and fosters formal collaborations tailored to achieving investigator-initiated research objectives.

The program coordinator for each IRPG group is designated by the group and must be the principal investigator of a component research project grant (R01). The program coordinator is responsible for, besides the responsibilities of a principal investigator, ensuring that the proposed collaborative interactions take place and shared resources are used optimally. This may be accomplished by meeting with all IRPG group investigators or by other means appropriate for the group.

Because each research project is an independent application, it must be prepared with the same detail and thoroughness required of any R01 or R29 application. Each project must stand on its own scientifically and could be accomplished independently. For example, one project must not be dependent on another project in the IRPG group for a critical chemical or reagent, testing or processing of key samples, or interpretation of data.

If there is a question about the appropriateness of a set of applications for an IRPG group, applicants are encouraged to discuss the issues with one of the NIH staff contacts listed under INQUIRIES.

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

It is NIH policy that women and members of minority groups and their subpopulations must be included in all NIH-supported biomedical research projects involving human subjects, unless a clear and compelling rationale and justification is provided that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This new policy is a result of the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43) and supersedes and strengthens previous policies - Concerning the Inclusion of Women in Study Populations - which have been in effect since 1990. The new policy contains some new provisions that are substantially different from the 1990 policies.

All investigators proposing research involving human subjects should read the "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research," which were published in the Federal Register, March 28, 1994 (FR 59 14508-14513), and printed in the NIH Guide for Grants and Contracts, March 18, 1994, Volume 23, Number 11. Investigators may obtain copies from these sources, from NIH program staff, or the individuals identified for each NIH institute or center listed in these instructions. Program staff may also provide additional relevant information concerning the policy.

APPLICATION PROCEDURES

Applications are to be submitted on the grant application form PHS 398 (rev. 5/95). These forms are available at most institutional offices of sponsored research and from the Office of Grants Information, Division of Research Grants, National Institutes of Health, 6701 Rockledge Drive, Room 3032, MSC 7762 Bethesda, MD 20892-7762, (301) 435-0714, FAX (301) 435-3963, E-mail GIRG@DRGPO.DRG.NIH.GOV.

FIRST applications (new and revised) must be accompanied by three letters of reference; FIRST applications without these letters will be considered incomplete and will be returned without review.

Each application must have its own descriptive title and a principal investigator. Each requested shared resource must be included in one of the component R01 or R29 applications; no shared resource may be submitted as a separate application. The contributions of all shared resources must be summarized in item (i) CONSULTANTS of the Research Plan, describing the collaborative interactions of the IRPG group. However, the detailed description and budget for each shared resource may be requested by only one application in each IRPG group, in the project most suited to oversee that resource activity. Item (i) must be complete, with enough detail for NIH staff and reviewers to understand the full scope of interactive collaborations within the IRPG group. Other component projects must NOT be included as appendix material.

Revisions --- Revised applications must include an Introduction and highlight the changes made in the Research Plan in response to the previous critique and describe in item (i) how the delay in initiating the collaboration will be managed. This is particularly important if some projects in the IRPG group were awarded and research on those projects has already begun.

Shared Resources --- A description of the shared resources that will be supported with a research project must be inserted separately in the application, after item (i) of the Research Plan. This must include an explicit description of the methods and procedures to be used, the services, tests, animals, or facilities to be provided, and a description of the involvement and protection of human subjects or vertebrate animals, if appropriate. Extensive shared resources or those with large budgets may be more appropriate as "cores" in program projects. Applicants are urged to contact an NIH staff member to discuss the nature and extent of proposed shared resources in an IRPG group.

The detailed description and budget request for a shared resource must be included in the R01 or R29 application of the principal investigator who will serve as the leader of that resource. If the proposed shared resource will be managed by an individual who is not the principal investigator of any of the components of the IRPG group, the shared resource component should be included in one of the IRPG applications according to the following instructions. Support for a shared resource must not be requested by a separate application.

o If the shared resource will be managed by a member of the research team of a component IRPG, the budget for the shared resource must be presented in that application.

o If the shared resource will be managed by someone (but not the principal investigator) employed by an applicant institution, the budget for the shared resource component must be presented in the component IRPG application from that institution. If there is more than one component IRPG application from that institution, the request for support of the shared resource must be included in the application of the principal investigator who will use that resource the most.

o If the shared resource is not located within an applicant institution, it may be supported by a contract from a component IRPG awardee. As above, support of the shared resource must be requested in the application of the principal investigator who will use the facility or resource the most.

o If all projects will share a remote resource equally, or if the request is to provide only fee-for-service testing or procedures, the costs may be included within each research project. Staff in the appropriate NIH institute or center should be contacted for further guidance in preparing these requests.

The appropriateness of each requested shared resource and the impact of its use by each project in the IRPG group will be evaluated separately from the proposed research project, and appropriate modifications may be recommended.

Instructions for Preparing Applications on the PHS 398 (rev. 5/95)

The following instructions address ONLY the parts of the PHS 398 research grant application form for which information about the proposed interactive research is requested. All other parts of the grant application should be prepared according to the instructions in the PHS 398 booklet (rev. 5/95).

Cover Letter: A cover letter that identifies the total number of applications in the IRPG group and the principal investigator for each must be enclosed in the package of applications.

FACE PAGE - AA:

Item 2. Mark "Yes" and enter the program announcement number and title,

Items 7-8. Enter the direct costs and total costs - includes the costs of the specific research project AND the costs of all "shared resources" to be supported through THIS application (see below for details concerning budget presentation).

Form BB:

Description. Provide a brief description (abstract) of the research proposed according to the instructions provided on page 10 of booklet for the PHS 398 (rev. 5/95). The description of the proposed IRPG interactions and/or any shared resources requested through this application may be included.

Performance Site(s). The performance site(s) of THIS project AND of any shared resource(s) in the IRPG group that will be used in this project (any involved institution should be named only once).

Key Personnel. List first the principal investigator and key personnel engaged on THIS project, followed by all key personnel engaged on any shared resource(s) to be supported by this project. Then list, as collaborators, all principal investigators and professional personnel engaged in all component projects and shared resources in the IRPG group.

Form CC:

TABLE OF CONTENTS. Add the page locations for Part 2 IRPG Interactions of item (i) of the Research Plan and for each of the shared resources proposed to be supported through this application.

Forms DD and EE:

Project Budget. Complete these pages as directed with the budget requests for this research project only. Do not include any shared resources here, since they will have separate budget pages. Provide clear justification for all items requested in the first year and for any significant increases or decreases in any category in future years.

Shared Resource Budgets(s). Complete a separate form DD and form EE for each shared resource facility or activity that will be supported through THIS project, do not include budgets for shared resources that will be supported through other projects in the IRPG group.
CLEARLY LABEL these form pages as "shared resource budgets" by typing the name of the shared resource in the upper left portion of the page.

Composite Budget. If any shared resources are requested as part of this application, form DD should be used to prepare a composite budget showing the requested total direct costs for the project and the shared resource(s). The dollar totals listed must match the amounts entered on Item 7 on the application face page (form AA). This composite budget will help reviewers and staff reconcile the figures on the face page with those in the body of the application.

Form FF:

The biographical sketch for each key investigator involved in the project AND any shared resource(s) to be supported by this project must be included.

Form GG:

Other support information for all professional staff involved in the project AND any shared resource(s) to be supported by this project must be included.

Form HH:

Besides completing form HH for the project, a separate form HH for each shared resource to be supported by the project, itemizing the facilities and major equipment that will be available to the IRPG group, must be completed.

RESEARCH PLAN:

The instructions in section C-9 (pages 15-19) of the PHS 398 must be followed to complete a. through d. (Page 16) of the Research Plan in detail. Attention may be given to the integration of the individual project into the overall IRPG group effort. The overall research plan (a.-d.) for the project may not exceed 25 pages. The following points may be addressed in the appropriate sections.

a. SPECIFIC AIMS. Besides listing the specific objectives of the individual research project for the total period of requested support, briefly summarize how the overall objective or long-term goal of the research relates to the goals of the IRPG group.

b. BACKGROUND AND SIGNIFICANCE. Besides discussing the overall scientific significance of the proposed research, this section may briefly summarize the relevance of the project to the scientific goals of the IRPG group.

(i) CONSULTANTS. Particular attention must be given in completing this section of the Research Plan. It must have subsections as follows: Part 1 of (i) must address the collaborations that are unique to the research proposed in this R01 or R29 application as an independent project. Part 2 must describe in detail the proposed interactions and collaborations within the IRPG group, and MUST BE IDENTICAL IN ALL COMPONENT APPLICATIONS OF THE IRPG GROUP.

PART 1. PROJECT SPECIFIC CONSULTANTS/COLLABORATORS. Section III.A.DEFINITIONS on page 24 of the PHS 398 Instructions should be consulted for help in determining what information to provide about consultants and collaborators who are proposed for the individual research project.

PART 2. IRPG INTERACTIONS. The collaborative efforts among components of the IRPG group must be described in this section. The description should be concise, although the number of pages is not restricted. However, this section must not be used to avoid the page limitations of the Research Plan in Sections a.-d. Each component R01 and R29 application of the IRPG group must contain IDENTICAL

GROUP STATEMENTS describing the collaborative efforts and the use of any requested shared resources. Preparing this section should be a joint effort among the participating principal investigators under the leadership of the Program Coordinator, who is responsible for coordinating the collaborative efforts among all of the IRPG principal investigators.

The following three items must be included in Part 2 IRPG INTERACTIONS:

1. IRPG COMPONENTS AND PARTICIPATING INVESTIGATORS. A list of every application that is part of the IRPG group, giving each an IRPG project number, and showing the type of application (R01 or R29), Project Title, and principal investigator must be provided. The Program Coordinator should also be identified here. The Program Coordinator must be the first investigator named on the list, with the title "Program Coordinator" following his/her name. For example:

IRPG one, R01, (project title), Jessica W. Smith, (Program Coordinator)
IRPG two, R29, (project title), (PI)
IRPG three, R01, (project title), (PI)

2. DESCRIPTION OF INTERACTIVE RESEARCH ACTIVITIES. This important item provides an opportunity for the IRPG group to give conceptual wholeness to the overall program. It must include discussion of the intended interactions among the IRPG component projects and describe how each shared resource will contribute to those interactions.

The general IRPG group objectives and the strategy for achieving those objectives must be described. As the strategy develops, each project and shared resource should be cited for its role in the overall scheme. Include a brief overview of the goals, objectives, rationale, and key methods and approaches for the research proposed in each project and shared resource. Describe how each relates to the scientific goals of the IRPG group and/or the anticipated approach to achieve the IRPG group goals. A diagram of the interrelationships of the projects and the enhancement of the collaborative efforts of the research projects by each shared resource may be helpful.

3. SUMMARY OF SHARED RESOURCES. If any shared resources are requested by the IRPG group, identical information about their use must be included in all applications of the IRPG group to aid in review of the application. The application should specify the anticipated percent of use of each shared resource in the entire IRPG group by each project in the IRPG group. This

information will provide reviewers, advisory council members, and NIH staff with a complete picture of the overall shared resource contribution to the IRPG group.

DESCRIPTION OF SHARED RESOURCES TO BE SUPPORTED BY THIS APPLICATION:
A new section must be added to the Research Plan, after (i) Consultants, for each shared resource to be supported by this application. The first page of this section should clearly show the descriptive title of the shared resource; the name, title and affiliation of the individual who will manage the shared resource; and the specific location (department, institution, city) of the shared resource.

A concise, but explicit and complete, description and justification for the shared resource requested. This section must present a clear picture of the approaches, methods, techniques, animals, and/or special populations that will be used to support each project in the IRPG group. Specifically address how the available resources and environment will be sufficient to address the needs of all of the projects in the IRPG group. If appropriate, address the involvement and protection of human subjects and/or vertebrate animals if that has not been addressed under (e) and (f) of the Research Plan of the project.

Application Receipt Dates

The receipt, review, and earliest possible award dates for unsolicited IRPG applications (except AIDS and AIDS-related), whether new, competing renewal, or revised, are as follows:

Application Receipt Date:	Feb 15	Jun 15	Oct 15
Initial Review:	Jun	Oct	Feb
Council Review:	Sep/Oct	Jan/Feb	May/Jun
Earliest Possible Award:	Dec 1	Apr 1	Jul 1

IRPG applications for research on AIDS and AIDS-related topics must be identified on the face page, item two, of the application. The receipt, review, and earliest possible award dates for AIDS and AIDS- related IRPG applications are as follows:

Application Receipt Date:	Jan 2	May 1	Sep 1
Initial Review:	Mar/Apr	Jul	
Nov Council Review:	May/Jun	Sep/Oct	Jan/Feb
Earliest Date of Award:	Jul 1	Dec 1	Apr 1

Application Submission

For each component of an IRPG group, a signed, typewritten original application, five exact single-sided copies, and five sets of appendix material must be submitted. Each application must be complete, with all approvals, budgets, and signatures from the appropriate officials of the applicant institution.

All of the R01 and R29 applications constituting the proposed IRPG group must be submitted in a single package, whether or not the applications are from the same institution. A cover letter must list the total number of applications submitted for the IRPG group, clearly identifying each application and the principal investigator of each. For each component application in the IRPG group, the original, five copies, and the appendix material must be bundled together and clearly identified. Failure to follow the instructions regarding application receipt dates and packaging may lead to a delay in review.

The complete IRPG group package must be sent or delivered to:

DIVISION OF RESEARCH GRANTS**
NATIONAL INSTITUTES OF HEALTH
6701 ROCKLEDGE DRIVE, ROOM 1040 MSC 7710
BETHESDA, MD 20892

**The NIH address for the receipt of grant applications. Applicants using overnight delivery or courier services should use the following zip code:

Bethesda, MD 20817-7710

Any questions regarding the format for submission of an IRPG may be directed to the Referral Office, DRG.

REVIEW CONSIDERATIONS

Upon receipt, applications and supporting material will be examined for completeness by the DRG. Incomplete applications will be returned without further consideration.

Each application in an IRPG group will be referred (assigned) independently according to standard PHS referral and review procedures for initial review of scientific and technical merit.

Because applications in the IRPG group might receive different assignments, the IRPG Interactions subsection of item (i) must be complete so that reviewers can understand the collaborations and interactions without seeing the other applications in the group.
Following scientific and technical merit review, applications will receive a second level of review by the national advisory council or board of the appropriate NIH institute or center.

Institute or center assignment of each component application of an IRPG group will also be governed by established PHS referral guidelines. Therefore, based on the subject matter, each component application of an IRPG group could be assigned to a different NIH institute or center for funding consideration. This underscores the need for each application to be complete and for all component applications to have identical subsections in the item (i) Part 2 IRPG Interactions of the Research Plan.

Reviewers will evaluate each component IRPG application using the standard review criteria for R01 and R29 applications:

o scientific significance and originality of the proposed work;

o appropriateness and adequacy of the approaches and methods proposed to carry out the research, as described in the Research Plan;

o qualifications and relevant research experience of the principal investigator and staff to do the proposed research;

o availability of resources necessary to conduct the research;

o inclusion of women and minorities in clinical studies

In addition, reviewers will assess the intended IRPG interactions. In an administrative note, the reviewers will indicate the effectiveness and feasibility of the proposed IRPG group interactions, whether or not they enhance the prospects for reaching the stated objectives of the group, and the extent of the synergy among the various projects. The appropriate national advisory council or board and institute or center program staff will consider these comments when making award decisions.

The criteria for the initial review of the shared resources requested for the IRPG group, which are reviewed independently from the research project, are the following:

o qualifications of key personnel;

o adequacy of approaches, methods, and facilities;

o appropriateness for the IRPG group; and

o use by component IRPGs.

The reviewers may also make recommendations about the shared resource(s) and the reasonableness of the budget request. These recommendations will be considered when funding decisions are made by the awarding institute or center. The amount awarded for shared resources may depend on the number of component projects awarded.

AWARD CRITERIA

Applications will compete for available funds with all other applications assigned to an Institute or Center. The following will be considered in making funding decisions:

o quality of the proposed project as determined by peer review;

o the interactive nature of the program and component IRPGs;

o availability of funds;

o program balance and priorities among research areas;

Each NIH institute or center will have the opportunity to fund some or all of the component R01s and R29s of an IRPG group assigned to that institute or center. If the component projects are assigned to more than one institute or center, co-funding may be considered. If any of the component projects in the IRPG group are considered not supportable, the collaborative plans may need to be modified or negotiated among the collaborators and/or awarding institute or center.

INQUIRIES

For information about application preparation, submission, and assignment of the IRPG applications, contact:

Referral Office
Division of Research Grants
(301) 435-0715

For further information about programmatic or scientific areas, any of the following individuals may be contacted:

Dr. Kenneth Warren
Director, Office of Scientific Affairs
National Institute on Alcohol Abuse and Alcoholism
(301) 443-4375

Dr. Miriam Kelty
Associate Director, Extramural Affairs
National Institute on Aging
(301) 4986-9322

Mr. Allan Czarra
Director, Office of Program Coordination and Operations
National Institute of Allergy and Infectious Diseases
(301) 496-7291

Dr. Michael Lockshin
Director, Extramural Programs
National Institute of Arthritis and Musculoskeletal and Skin Diseases
(301) 496-0802

Dr. Marvin Kalt
Director, Division of Extramural Activities
National Cancer Institute
(301) 496-4218

Ms. Hildegard Topper
Special Assistant to the Deputy Director

National Institute of Child Health and Human Development
(301) 496-0104

Dr. Norman Braveman
Assistant Director for Program Development
National Institute of Dental Research
(301) 594-7648

Dr. Walter Stolz
Director, Division of Extramural Activities
National Institute of Diabetes and Digestive and Kidney Diseases
(301) 594-7277

Dr. Thor Fjellstedt
Deputy Director, Division of Extramural Research and Training
National Institute of Environmental Health Sciences
(919) 541-0131

Dr. Milton Corn
Acting Associate Director, Division of Extramural Programs
National Library of Medicine
(301) 496-4621

Dr. Hugh Stamper
Director, Division of Extramural Activities
National Institute of Mental Health
(301) 443-3367

Director, Division of Extramural Programs
National Institute of Nursing Research
(301) 594-7590

Dr. Louise Ramm
Deputy Director
National Center for Research Resources
(301) 594-0630

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance Nos. 93.113, 93.114, 93.115, 93.121, 93.198, 93.306, 93.333, 93.371, 93.393, 93.394, 93.395, 93.396, 93.397, 93.847, 93.848, 93.849, 93.855, 93.856, 93.864, 93.865, 93.929, 93.866, 93.879, 93.361, 93.846, 93.242, 93.273, and 93.279. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

The PHS strongly encourages all grant and contract recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

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